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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/668,196      | 09/22/2000  | Stephen James Russell | 18093/1130          | 9873             |

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EXAMINER

BRUMBACK, BRENDA G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 08/16/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/668,196

Applicant(s)

RUSSELL ET AL.

Examiner

Brenda G. Brumback

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9,11-22,24,26 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 11-22, 24, 26 and 28-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

This action is responsive to the amendment filed 06/07/2000.

Claims 8, 10, 23, 25, and 27 have been canceled. Claims 1-7, 9, 11-18, 20-22, and 28-30 have been amended. New claim 33 was added. Claims 1-7, 9, 11-22, 24, 26, and 28-33 are pending and under examination on the merits.

#### ***Information Disclosure Statement***

The Supplemental Information Disclosure Statement filed 07/12/2002 has been considered. A signed copy of the PTO-1449 form is attached hereto.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 1-7, 9, 11-22, 24, 26, and 28-32 under 35 U.S.C. 112, second paragraph, is withdrawn pursuant to applicant's amendment thereof and arguments, which were persuasive.

The term "about" in claim 10 is understood to mean the recited value within the typical error parameters associated with titrating techniques as is outlined in applicant's response filed 06/07/2000 and "non-human cells" is understood to mean that the cells include, but are "not limited to chick embryos, quail embryos, duck embryos, and dog and bovine kidney cells" as is disclosed in the specification at page 14, lines 15-17.

The rejection of claims 1-7, 9, 11-22, 24, 26, and 28-32 under 35 U.S.C. 112, first paragraph, is withdrawn subsequent to applicant's amendment thereof.

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***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-3 and 23 under 35 U.S.C. 103(a) as being unpatentable over either of Bateman et al. or Linardakis et al. is maintained for claims 1-3 for the reasons of record. Applicant's arguments have been fully considered but they are not persuasive for the following reasons.

Applicant argues that Bateman et al. "says nothing about the ability of whole measles virus to reduce the number of viable cancer cells in a mammal". Applicant is referred to the first sentence of Bateman abstract, wherein Bateman teaches that the fusogenic membrane glycoproteins of measles virus have a direct cytotoxic effect by killing cells due to the formation of syncytia, and the second paragraph, wherein Bateman teaches that this effect spreads to neighboring cells. Thus, although Bateman does teach that tumor-associated FMG expression generates a specific anti-tumor immunity (first sentence of the abstract), Bateman also teaches that the fusogenic membrane glycoproteins of measles kill tumor cells directly. Since whole attenuated measles virus comprises the membrane glycoproteins and causes cell death due to the formation of large multinucleated syncytial cells by the viral membrane fusogenic proteins, the teachings of Bateman point directly to the claimed method of reducing the number of viable cancer cells in a mammal by administration of an attenuated measles virus. Even if this were not the case, applicant's claims are drawn to reduction of the number of viable cancer cells, and do not recite the causative mechanism of the reduction. Reduction of the number of viable cancer cells occurs as a result of an anti-tumor immune response, as well as from formation of non-viable syncytial cells.

Applicant argues that the macromolecular interactions between and among the fusogenic membrane proteins (FMG) is "far different" from those present in the arrays of specifically oriented multi-protein aggregates constituting a whole virus" and "As such the observed cytotoxic effects of FMGs expressed in tumor cells *in vitro* have little, if any, relevance to whole measles virus". However, it is well

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known in the art that the cytotoxic effects caused by measles virus, which consist of the formation of non-viable large multinucleated syncytial cells, is affected through the FMGs on the surface of the virion.

Even the name "fusogenic membrane glycoprotein" clearly points this out. Thus, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation that whole attenuated measles virus would have possessed the same fusogenic properties as those of the isolated FMGs.

Applicant has provided no evidence to the contrary. Argument in the absence of evidence is not persuasive.

The rejection of claims 1-25 and 28-32 under 35 U.S.C. 103(a) as being unpatentable over Bateman et al. in view of Weibel et al. is maintained for claims 1-7, 9, 11-22, 24, and 28-32 and newly applied to claim 33 for the reasons of record. Applicant's arguments have been fully considered but they are not persuasive.

Applicant's argues that the combination of the references does not provide a reasonable expectation of success in delivering FMGs *in vivo* using attenuated measles virus because Bateman teaches transfecting cells *in vitro*. However, Bateman clearly teaches application of the FMGs for tumor reduction *in vivo*. See the first sentence of the abstract, for example, wherein Bateman teaches "the use of viral fusogenic membrane glycoproteins (FMGs) as a new class of therapeutic genes for the control of tumor growth". The teachings of Bateman that the measles virus contains FMGs which are responsible for syncytial formation and that FMGs are effective for reducing tumor growth (and hence the number of viable cancer cells) *in vivo* due to the combined mechanisms of syncytial formation and the generation of anti-tumor immunity combined with the teachings of Weibel that preparations of attenuated viable vaccine strains of measles virus are commercially available and routinely administered, one of ordinary skill in the art would have had a reasonable expectation of success for reducing tumor growth in a

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mammal by administration of an attenuated measles vaccine strain. Applicant's argument regarding the relationship of the molecular biology between the whole virus and the FMGs has been addressed *supra*.

The rejection of claims 1-17, 20-24, 26-28, and 30-32 under 35 U.S.C. 103(a) as being unpatentable over Bateman 2000 in view of Sunnis et al. is maintained for claims 1-7, 9, 11-22, 24, 26, and 28-32 and newly applied to claim 33 for the reasons of record; the rejection of claims 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over either of Bateman et al. in view of Weibel et al. or Bateman et al. in view of Usonis et al. and further in view of Duprex et al. is maintained; and the rejection of claim 20 under 35 U.S.C. 103(a) as being unpatentable over either of Galanis et al. or Russell et al. in view of either Weibel et al. or Usonis et al. are all maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant's arguments are essentially the same as those presented in response to the rejection over Bateman 2000 in view of Weibel et al. and have been previously addressed.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Official FAX telephone number is (703) 872-9306 and the After Final FAX telephone number is (703) 872-9307. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

August 15, 2002

*Brenda Brumback*  
Brenda Brumback  
Primary Examiner